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8EHQ-0103-15261

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8EHQ-03-15261

January 15, 2003

VIA CERTIFIED MAIL

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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460



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ATTN: TSCA Section 8(e) Coordinator

RE: Submission of An Oral Two-Generation Reproductive, Fertility, and Developmental Neurobehavioral Study in Rats Using Tetrabromobisphenol-A (CAS No.: 79-94-7)

Dear TSCA 8(e) Coordinator:

The Brominated Flame Retardants Industry Panel (BFRIP)¹ of the American Chemistry Council is submitting the enclosed oral two-generation reproductive, fertility, and developmental neurobehavioral study in rats. The study was performed using Tetrabromobisphenol-A (TBBPA, CAS No.: 79-94-7). The enclosed study was undertaken and recently completed and submitted to the European Union (EU) in the context of the EU's on-going risk assessment of TBBPA.

The results of the study are corroborative of information previously reported to the U.S. Environmental Protection Agency (EPA). As such, BFRIP has not concluded that reporting is required pursuant to the requirements of Section 8(e) of the Toxic Substances Control Act (TSCA). Nevertheless, the study is being submitted under TSCA 8(e) out of an abundance of caution because a microscopic evaluation performed on 10 pre-selected (Day 11 F₂) offspring of test animals treated at the highest dose level studied showed a reduction in the thickness of the parietal cortex. This finding was not associated with any histology changes. No similar microscopic findings were observed in the brain, spinal cord, nerves, and ganglia of another 10

¹ The members of BFRIP include Albemarle Corporation, Ameribrom, Inc. - Dead Sea Bromine Group and Great Lakes Chemical Corporation.

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pre-selected (Day 60 F₂) offspring of test animals treated at the same dose level. Furthermore, no other developmental or neurobehavioral effects were seen in any of the other F₂ offspring of test animals treated at the highest dose level or the two lower doses. Thus, the decreased thickness of the parietal cortex seen in the 10 pre-selected Day 11 F₂ offspring is considered a subtle morphometric change without supporting clinical, developmental and/or neurobehavioral effects.

If you have any questions, please feel free to contact Wendy Sherman, American Chemistry Council's Brominated Flame Retardant Industry Panel Manager at (703) 741-5639 or via email at [wendy_sherman@americanchemistry.com].

Sincerely,

Barbara Francis

JA Susan A. Lewis, Ph. D.
Managing Director, CHEMSTAR
American Chemistry Council

Enclosure: Study on CD-ROM